UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. RENÉE MARIE BUMB** **CIVIL NO. 19-2875 (RMB)**
THIS DOCUMENT RELATES TO ALL CASES	

TPP TRIAL PLAINTIFFS' BRIEF REGARDING TRIAL CLAIMS, DAMAGES, AND MIL 16

I. THE WARRANTIES TO BE PRESENTED TO THE JURY

The primary warranty at issue in this trial is the labeling-based representations by the Defendants that they were selling FDA approved, Orange Book A/B rated, USP compliant valsartan that was manufactured in a manner that was compliant with cGMPs and was not adulterated. These are separate, distinct warranties that the jury may find breached. The Court has already ruled that this labeling-based representation constituted an express warranty as a matter of law:

> The Court finds that the issue of whether Ds statements, wherever expressed, were warranties is not genuinely disputed and is a material fact. The Court agrees with its MTD 3 Opinion and with Ps declarations (SJ Omni Brf.:7) that Ds labelling of the VCDs as valsartan constituted an express warranty. Accordingly, the Court GRANTS plaintiffs' Omnibus motion for summary judgment (Doc. 2569) on the issue that defendants' affirmations, statements, labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the RLD.

(SJ Op., at 29 (emphasis added).) (Dkt. No. 2694).

Defendants' own corporate witnesses have confirmed extensive related and overlapping representations to the same effect to their customers. For example, ZHP witnesses testified that every pill that was sold was accompanied by those representations. *See* Dkt. No. 2569-3 (ZHP SOMF) ¶¶135-154. ZHP witnesses explained what was conveyed to consumers and TPPs was that the VCDs were "high quality, manufactured in a state of the art GMP facility that applies the highest quality assurance standards that meet the FDA regulatory requirements," and that, "when people buy products from Prinston and Solco that they trust that the products

are what they're supposed to be[.]" (Hai Wang 3/10/21 Dep. Tr., 44:12-21, 47:5-13). ZHP further warranted to its finished-dose customers that the latter were buying API free of nitrosamine impurities). (Jie Wang 5/19/21 Dep. Tr., 185:20-186:11).[1] Finally, Plaintiffs' claims have never been based on a representation that they were to be sold "low cost" drugs.[2]

II. PLAINTIFFS' TRIAL CLAIMS AND ELEMENTS TO BE PRESENTED

1. The Express Warranty, Fraud, and CPL Claims

The claims at trial include express warranty, fraud, and consumer protection law ("CPL") claims, and all are based on the ***same*** false representations:

> Grounded in the failure to comply with cGMPs or compendial standards, legal claims against generic drug mfrs can include breach of express warranty, violation of consumer protection laws, and fraud. And, these claims are precisely what Ps have asserted against ZHP as the API mfr and Teva and Torrent as the FD mfrs.

(SJ Op., at 26 (Dkt. No. 2694).)

a. Express Warranty:

The elements of breach of express warranty are: (1) the existence of a warranty that formed a basis of the bargain; (2) breach of that warranty (i.e., non-

[1] This was similarly true for Teva and Torrent. *See, e.g.,* Dkt. Nos. 2563 (Teva SOMF) at ¶¶ 37-40, and 2566 (Torrent SOMF) at ¶¶ 32, 36-37, 55.

[2] Dr. Stiroh herself reluctantly admitted that TPPs have an interest in paying for safe and effective medications for their plan members, which is contrary to the very foundations of her proferred opinions in this case. (*Compare* 9/10/24 Hrg Tr. 30:12-21 *with* 9/9/24 Hrg Tr. 53:22-55:7 (defense counsel admitting assumption that TPPs "don't care what they buy" is a critical "part of Dr. Stiroh's methodology")).

conformance of the good(s) to the warranty); and (3) resulting damages.

Knowledge or scienter is not an element of the warranty claim.[3] 1 THE LAW OF PROD. WARRANTIES § 4:1, *The Impact of § 2-313- General Principles Governing Express Warranties* ("By contrast, § 2-313 imposes ***a kind of strict liability***, in the sense that affirmations of fact, promises, descriptions, samples, and models of goods may amount to express warranties without the slightest trace of tortious misrepresentation.") (Feb. 2024 update) (emphasis added). Nor is any showing of *scienter* consistent with how the law instructs express warranty damages to be calculated. All Express Warranty subclass "b" jurisdictions have enacted identical versions of UCC § 2-714,[4] which specifies the objective damages rubric as follows:

> The measure of damages for breach of warranty is the difference **at the time and place of acceptance** between the value of the goods accepted and the value they would have had if they had been as warranted.

Defendants have never once argued that any jurisdiction requires *scienter* or knowledge on the part of the Defendant to prove any element of this claim, including damages, and that should not be required here.

All Plaintiffs must prove is that the VCDs did not "conform" to the labeling-based warranty, by for example, having been contaminated and/or adulterated, and

[3] (*See* App'x, Part I (citations to Express Warranty Subclass "b" authorities that *scienter* is not required).)
[4] (*See* App'x, Part II (citations to Express Warranty Subclass "b" state enactments of UCC § 2-714).)

thus were not therapeutically equivalent, CGMP- and/or USP-compliant. (SJ Op., at 31-32 ("If undisputed facts show adulteration, then Ds representations that their VCDs were equivalent to the RLD were false, which demonstrates a breach of express warranty."). Once Plaintiffs prove breach, the jury will determine damages under the "benefit of the bargain" damages rubric agreed to by Defendants.

b. CPL Claims

The Court's class certification opinion grouped the selected CPL Subclass "a" states on a finding that none of these jurisdictions include a *scienter* requirement,[5] which finding was reaffirmed in the Court's summary judgment opinion:

> As a CPL claim requires deceptive or unfair conduct that can amount to a material misrepresentation or omission likely to mislead but **does not require the defendant's knowledge or intent that the misrepresentation will mislead**, violation of consumer protection laws, while often termed "consumer fraud", need not rise to the level of fraud.

(SJ Op., at 48) (emphasis added).

The core elements of the CPL claims include "deception" (*i.e.,* likely to mislead a reasonable person regardless of defendant's intent) or "unfairness" (weighing substantiality of injury to any countervailing benefits and whether plaintiff could have avoided the injury with reasonable diligence), in these jurisdictions. This Court has likewise previously found that Plaintiffs' descriptions

[5] (*See* App'x, at Part III (citations to CPL Subclass "a" authorities that claims do not require a showing of *scienter*).)

legal descriptions of CPL Subclass "a" states accurately define these core liability elements (SJ Op., at 49 ("The Court finds that Ps have cited correct, supporting caselaw of the standards in TPP CPL subclass a[.]").) Further explanation and authorities are in the proposed jury instructions. (Dkt. Nos. 2683-84 (Pls' Proposed CPL Instructions 6.3 & 6.4)). And the damages are subject to being trebled.

c. Common Law Fraud

As this Court has correctly observed, "the basic elements [of a fraud claim] are virtually the same" across all jurisdictions. (*See* Dkt. No. 818 (MTD Op. 5, at 12).) Those proof elements are: (1) a materially false representation of fact; (2) made by the defendant; (3) with the relevant *scienter* showing; (4) on which the plaintiff placed justifiable reliance; and (5) resulting injury and damages.

TPP Plaintiffs rely on the false representations as with the express warranty claims as well as other statements and documents demonstrating knowledge and falsity. Plaintiffs must therefore prove those representations to have been materially false, and that the Defendants knew or believed them to be false or were aware that their representations were made without adequate knowledge as to whether those statements were true or false (*i.e., scienter*).[6] The material nature of the false representation is evident in the record. Defendants acknowledge NDMA and NDEA

[6] (*See* App'x, at Part IV (describing common law fraud *scienter* in all fraud subclass "c" states).)

to be probable human carcinogens, and that VCDs containing its contaminated API posed an "unacceptable carcinogenic risk[.]" All three (3) Defendants "*voluntarily*" recalled their VCDs. And finally, the FDA found the API to be adulterated and imposed an import ban on ZHP for years.

Finally, for these fraud claims, Plaintiffs must prove reliance and damages. TPPs will present fact and expert testimony regarding how TPPs justifiably rely on prescription drug approvals and labeling, and indeed, this Court has found previously that TPPs "had no choice but to 'rely'" on said labeling and everything that labeling conveyed. (MTD Op. 3, at 14; SJ Op., at 29 (reaffirming findings of MTD 3)). Using Defendant ZHP as an example, as to damages, even if *scienter* is only found beginning on July 27, 2017 (the date of the email referencing the contamination and the root cause for the contamination), the damages against ZHP alone are approximately $446 million. Plaintiffs also seek punitive damages for this reprehensible conduct.

III. THE DAMAGES THAT RESULT FROM PLAINTIFFS' CLAIMS

The damages analysis will proceed pursuant to the benefit of the bargain approach, as agreed by the Defendants. (MTD Op. 2, at 8-15 (Dkt. No. 728)). Importantly, this Court has previously found in this case that zero value or "full reimbursement" damages are permissible under a benefit of the bargain theory:

> Because the VCDs were not as Defendants represented and warranted—that is, they were adulterated, misbranded, non cGMP

> compliant, and illegal to sell—**Plaintiffs did not receive the benefit of their bargain and suffered economic loss by receiving a worthless product.**
> …
> Under this theory, **Plaintiffs seek reimbursement for the full amount paid for the VCDs, that is, their out-of-pocket expenditures**. This is not some amorphous allegation of an economic loss lacking a concrete way of calculating it. This allegation suffices for a factfinder to value Plaintiffs' purported economic injury

(MTD Op. 2, at 8-15 (Dkt. No. 728). (emphasis added)

It is important to recognize that each purchase was premised on each pill having **all** of the warranted, FDA approved and specified attributes in one integrated whole: safety, quality, purity, identity, and strength. **The pill has value only where all of the required attributes are present**. These attributes cannot be separately valued and purchased. The purchaser would not, and could not, buy the pills - and the TPP would not agree to pay - if the manufacturer disclosed that the pills lacked any one of those attributes because only the approved form of the drug can be lawfully sold.[7] This is a value judgment by Congress in determining that only drugs that are shown to be safe and effective, and which meet the continuing quality requirements so as to be non-adulterated, can have legal market value. As stated by the Eleventh Circuit Court of Appeals:

[7] Defendants' theory that the efficacy of the pills, retrospectively considered, provided value, is divorced from the reality that the required attributes of the pill cannot be deconstructed and separately valued. If Defendants are permitted to advance this argument they will have to overcome the reality of the true basis for the bargain and valuation of the pill as a whole, at the time of purchase.

> A person who purchased an adulterated dietary supplement thus received a product that Congress judged insufficiently safe for human ingestion. Given Congress's judgment, we conclude that the purchaser of such a supplement received a defective product that had no value. ***This conclusion is consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless***.

Debernardis v. IQ Formulations, LLC, 942 F.3d 1076, 1085 (11th Cir. 2019) (emphasis added).

The benefit of the bargain damages structure measures the difference in value between (1) the value of what was bargained for, and (2) the value of what was actually received, **measured at the time the transaction occurred (here, the point of sale)**. *See, e.g.,* UCC § 2-714 & App'x, at Part II ("[T]he measure of damages for breach of warranty is the difference **at the time and place of acceptance** between the value of the goods accepted and the value they would have had if they had been as warranted[.]" (emphasis added)). That is the point of sale (i.e., the pharmacy counter). (9/9/24 CMC Tr., at 133:25-134:9, 135:19-24.) Plaintiffs supply authorities from every Express Warranty Subclass "a" state demonstrating that "full reimbursement" damages are available under those states benefit-of-the-bargain damages laws. (*See* App'x, at Part V (collecting authorities from Express Warranty subclass "b" jurisdictions where zero value or "full reimbursement" damages have been recognized under those states' benefit of the bargain damages measures).)

"Full reimbursement" damages are generally available when the false representation "*tainted the purchasing decision*" of the plaintiff, where the plaintiff has been denied the "*essence*" of their bargain, *or where the defect fundamentally affects the intended use of the product, even though the product nevertheless provided some residual value and the plaintiff may have received some benefit*. (*e.g.,* in the Court's hypothetical, a plaintiff who purchased a counterfeit COACH® bag would be entitled to the full price paid as damages). This is a jury question here based on the Court's rulings. Some examples in the caselaw include:

- *In re Morning Song Bird Food Litig.*, No. 12CV01592 JAH-AGS, 2017 WL 1191485, at *14 (S.D. Cal. Mar. 31, 2017). (Defendant sold bird seed that contained pesticides, rendering it poisonous to birds. That the plaintiffs (and their avian visitors) nevertheless consumed the bird seed and obtained caloric nutrition did not undermine the full refund theory. The purchasing decision itself was tainted. The Court found the "full refund" damages methodology appropriate.)
- *In re JUUL Labs, Inc., Mktg. Sales Pracs. & Prod. Liab. Litig.,* 609 F. Supp. 3d 942, 976 (N.D. Cal. 2022) (approving plaintiffs' damages theory that, "because it was illegal or inherently unfair to market and sell the JUUL product to youth, youth purchasers received no value from it at all").
- *FTC v. Figgie Int'l, Inc.*, 994 F.2d 595, 606 (9th Cir. 1993). (Consumers entitled to "full refund" for heat detectors sold based on false representations, but which still functioned, just not as well as advertised: "To understand why [a full refund is appropriate even when the product maintains a modicum of value], we return to the hypothetical of the dishonest rhinestone merchant. Customers who purchased rhinestones sold as diamonds should have the opportunity to get all of their money back. The seller's misrepresentations tainted the customer's purchasing decisions.").
- *Makaeff v. Trump Univ., LLC*, 309 F.R.D. 631, 638 (S.D. Cal. 2015) (rejecting defendant's argument that full reimbursement would create an "undue windfall" because the students did obtain "knowledge and experience" despite the university's failure to provide the "essence of what they were promised.")

- *Steroid Hormone Prod. Cases*, 181 Cal. App. 4th, 145, 159-60 (Cal. App. 2nd Dist. 2010) (anabolic steroids illegally sold over the counter without prescription were economically worthless despite no allegation that they were not effective for their intended use).
- *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) (approving zero value damages model where probiotic nutritional supplement did not work as advertised and holding that "whether purchasers were nevertheless satisfied with [the product] does not affect the propriety of a full-refund damages model").
- *Chapman v. Tristar Prod., Inc.*, No. 1:16-CV-1114, 2017 WL 1433259, at *8 (N.D. Ohio Apr. 24, 2017) (case involving pressure cookers that would open while still under pressure, but otherwise functioned, and certifying Ohio express warranty class finding that Plaintiffs' theory that the "Pressure Cookers are unreasonably dangerous and therefore worthless" damages model satisfied *Comcast* and fit the facts of the case).
- *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 1:19-md-2875 (D.N.J.) (Dkt. No. 775) ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.").

Numerous courts have found that *already-consumed* drugs, supplements, food products, etc., are economically worthless regardless of (1) whether they provided any medical or other benefit (or at least recognized that a factfinder may validly so determine), and (2) whether they had been adjudicated adulterated at the time of purchase, and there is no *scienter* requirement:

- *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1084-85 (11th Cir. 2019) (in discussing *already purchased and consumed* dietary supplements, "a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value")
- *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. CV 13-4663, 2019 WL 4751883, at *8 (E.D. Pa. Sept. 30, 2019) (Dr. Conti was allowed to opine that the non-compliant drugs at issue had zero value even though they had been sold and used prior to any determination of adulteration).

- *Davis v. Main St. Fam. Pharmacy, LLC*, No. 5:16CV45-MW/GRJ, 2016 WL 9051172, at *3 (N.D. Fla. May 19, 2016) ("The adulterated [prescription] injection was worthless, and neither Davis nor anyone else in their right mind would have paid any money for it had they known that it was adulterated.").
- *In re Recalled Abbott Infant Formula Prod. Liab. Litig.*, 97 F.4th 525, 530 (7th Cir. 2024) ("A universal defect inherent in a product—such as a design defect or a fundamental flaw—renders each product valueless to each plaintiff, as in *Aqua Dots* and similar cases.").
- *United States v. Milstein,* 401 F.3d 53, 74 (2d Cir.2005) (*per curiam*) ("The district court may permissibly reason that [already-ingested] contaminated medicine is worthless to the consumer.")
- *United States v. Gonzalez–Alvarez,* 277 F.3d 73, 77–80 (1st Cir. 2002) (197,906 liters of sold and consumed milk later found to have been adulterated, which "cannot be sold lawfully[,] ... has a value of zero")
- *McMonigle v. BlackOxygen Organics USA, Inc.*, No. 1:21-CV-04790-LMM, 2022 WL 17908701, at *3 (N.D. Ga. Oct. 17, 2022) (finding that already-purchased and consumed nutritional supplements that were "adulterated with heavy metals" were "worthless as a matter of federal law.").

Here, Defendants' VCDs posed an "unacceptable carcinogenic risk" and were recalled.[8] Defendants' own witnesses admitted they *never would have sold* these drugs had they known of the contamination. And, as this Court has determined, the jury may likewise find that the Defendants' VCDs were adulterated from day one. (SJ Op., at 55-56 ("[A]duleration of the VCDs is a question for the fact-finder'); 57-58 ("To be clear, the Court holds that, just as fact-finders in U.S. federal district courts decide every day whether U.S. statutes and their accompanying Code of Federal Regulations have been violated, so too the TPP trial fact-finder here may

[8] To clarify a discussion at the hearing, the VCDs were not allowed to be sold after the recall. The FDA merely advised patients not to stop taking their VCD's until they could obtain non-adulterated drugs.

weigh the parties' facts and arguments to decide whether [and at what point in time] the VCDs were adulterated."). Even without a finding of adulteration from day one, the jury may still validly determine that these contaminated VCDs contained a fundamental defect that rendered them valueless, that the undisclosed defect tainted the entire purchasing decision, and/or deprived TPPs of the essence of their expected bargain and award full reimbursement damages under the benefit of the bargain theory.

The Federal Food Drug and Cosmetic Act ("FCDA") requires that prescription drugs be affirmatively demonstrated throughout the lifecycle to have the quality, purity, safety, and efficacy characteristics represented. (9/9/24 CMC Tr., at 65:24-66:10.) As demonstrated above, these attributes are mandatory and non-severable as a matter of reality and federal law and the governing regulations. The manufacturer is required to certify and maintain compliance with cGMPs and guarantee therapeutic equivalence through the Orange Book and approved labeling. (9/9/24 CMC Tr., at 73:9-22, 65:24-66:17, 75:13-76:2). Congress has determined that drugs that do not meet these non-severable requirements cannot be lawfully sold.

For clarity and to address a question raised by the Court, Dr. Conti assumed that the jury will determine that the drugs were worthless as the basis for her damages calculations here. That assumption is not new and is the basis for her calculation of

full value damages using the "gold standard" IQVIA pricing data.[9] However, in addition to assuming this, Dr. Conti has opined that, as a matter of economic principles, the contaminated VCDs were economically worthless at the point of sale (which opinion previously survived a *Daubert* challenge in *this* case as well as in *BCBS*).[10]

Dr. Conti can (1) explain the FDA's prohibition on the sale of adulterated drugs, (2) point to and rely on the FDA's finding that the contaminated drugs were adulterated, requiring a recall, (3) discuss the applicable economic principles including that there is no legitimate supply curve for the sale of adulterated drugs, and (4) present her damages calculations premised on the assumption of no value, and explain how the jury can use the numbers if it finds there was some value. This can be countered by Dr. Stiroh's opinion that the contaminated pills had theoretical value in retrospect due to the assumed therapeutic benefit of the contaminated drugs,

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[9] (*See* App'x, at Part VI for the numerous court decisions upholding the use of IQVIA pricing data for measuring damages)); *see also* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/2022-bibliography/iqvia-institute-advancing-academic-research-2022-10-22-forweb.pdf (listing at pp. 17-21 dozens of peer-reviewed publications published in 2021-2022 using IQVIA data including pricing data) (last visited Sept. 17, 2024).

[10] *See* Dkt. No. 2261, Class Cert. Op., at 88 ("The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, *i.e.*, mathematical model, which, … may reliably support her presumption of the worthlessness of the sold VCDs … The *BCBS* Court [also] found that not only was Dr. Conti's theory of 'worthlessness' appropriate but also her methodology in adopting and justifying the theory was reliable.").

as permitted by the Court. *If one of the experts is qualified to opine on value, both are*. The question of whether there was retrospective value to the pills based on their asserted efficacy is now a question for the jury, who may reject or accept the parties' competing propositions based on the evidence and as instructed on the law. At the very least, even if the Court will not let the experts give opinions on whether there was value, the experts can explain the controlling economic principles of pharmaceutical drug sales and their application. Dr. Conti can present her damages calculations, and the jury can decide having been instructed on the applicable legal principles. In this context, it is undisputed that Plaintiffs never would have accepted, and Defendants never would or should have sold, the contaminated pills, had the truth been disclosed.[11] *Davis*, 2016 WL 9051172, at *3.

a. The Court Should Continue to Reject The Alternative Drugs Defense[12]

The Court has rightly determined that Defendants' alternative drug defense fails as a matter of law. (*See* SJ Op., at 61-62 (citing and discussing *BCBS* opinion reaching the same conclusion).) The Court again reached the same conclusion at the September 9 CMC. (9/9/24 Hrg Tr., at 52:16-21 ("I don't accept the argument that, well, the plaintiffs, you know, get zero because they would have had to buy

[11] The Court previously rejected Defendants' efforts to avoid pre-recall findings of adulteration as relying on "sophistry." (Dkt. No. 2581, at 17).
[12] Plaintiffs incorporate by reference their prior briefing on this topic. (Dkt. Nos. 2811, 2822.)

alternative drugs. I don't find that persuasive.); *id.* at 53:12-13 ("I'm not going to let you present that argument to the jury[.]").)

At most, and over Plaintiffs' objection, the Court may permit Dr. Stiroh to assume the pills were effective (as an economist she cannot come to this conclusion on her own), while ignoring that effectiveness in the absence of safety, quality, and purity could never be the basis for the bargain in the sale of regulated, approved prescription pills. And importantly, Dr. Stiroh conceded that TPPs do have an interest in paying for safe and effective non-adulterated FDA-approved medications for their plan members, when presented with the Court's placebo hypothetical (and that is all that they agreed to pay for per their vetted formulary lists - which only permitted purchase of the warranted FDA approved, USP compliant valsartan).[13]

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Respectfully submitted,

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[13] Although not part of Plaintiffs' damages theory here, TPPs have to reimburse for additional monitoring due to the fact that their plan members were exposed to potent carcinogens, and may ultimately have to reimburse for *very expensive* cancer treatments in the event any of their plan members get diagnosed with cancer due to the exposure.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 18, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ David J. Stanoch